REMARKS

Claims 38, 42 and 53-62 were pending in this application, and were the subject of the office action dated December 11, 2007. Claims 38, 42, 55, 57, 59, 61 and 62 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,458,119 (Berenstein). Claims 38 and 53-57 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,432,126 (Gambale). Claims 53, 54 and 58 were rejected under 35 U.S.C. § 103(a) as being obvious over Berenstein, further in view of U.S. Patent No. 6,113,629 (Ken). Claims 56 and 60 were rejected under 35 U.S.C. § 103(a) as being obvious over Berenstein, further in view of U.S. Patent No. 5,690,671 (McGurk).

In response to the office action dated December 11, 2007, applicant has amended claims 38 and 42, and added new claims 63-65. Claims 38 and 42 are independent claims, with the remaining claims being dependent from one or the other of these two claims.

Reconsideration of the rejection is respectfully requested in view of the foregoing amendment and the following arguments.

Applicant's Invention

Applicant's invention is directed to a tissue implant that induces angiogenesis (growth of new blood vessels) in the tissue in which it is implanted, while also applying a therapeutic material. The implant comprises a scaffold structure that can be embedded or implanted within tissue and retained within the tissue by virtue of its geometry. The scaffold structure is configured to mechanically trigger an injury response in the tissue that leads to angiogenesis in that tissue. The invention also includes thrombus that is associated with the implant to enhance the angiogenesis effect and, further, the thrombus serves as a host matrix for another therapeutic material. The scaffold structure typically is sufficiently rigid to support the surrounding tissue and to prevent the surrounding tissue from collapsing the structure when the structure is implanted within the tissue. In one embodiment, anchoring of the structure within tissue is accomplished by providing the

structure with openings that permit herniation of tissue within the structure. Various types of scaffold structures which permit such herniation are disclosed and claimed. These openings also enable communication between a thrombus and therapeutic material disposed within the structure, and surrounding tissue.

Both of claims 38 and 42 have been amended to recite "the scaffold structure being sufficiently rigid to support surrounding tissue and to prevent surrounding tissue from collapsing the scaffold structure when the scaffold structure is implanted within tissue". Support for this added limitation is found in various locations throughout the specification, and more particularly at page 11, lines 17-19 and at page 16, lines 4-6. New claims 63 and 65 are dependent from claims 38 and 42 respectively. Each claim recites "wherein the scaffold structure comprises openings that permit herniation of tissue to anchor the scaffold structure within tissue." Support for this limitation is found throughout the specification, and more particularly at page 11, lines 24-26. New claim 64 recites that "the thrombus is disposed around the exterior of the device." This limitation was deleted from claim 38 and added to claim 64, which is dependent therefrom.

Berenstein

The Berenstein patent describes a vaso-occlusive device intended to be placed within the flow passage of a blood vessel for the purpose of obstructing the blood vessel and preventing blood flow downstream of the device. The device disclosed in Berenstein is long, thin and threadlike, and has little rigidity or column strength. (See col. 3, lines 15-18). After introduction, the device "quickly compacts into a significantly denser mass". (See col. 3, lines 37-38). Because of the flexibility and lack of column strength of the devices, the Berenstein devices are extremely soft and flexible and "exert little if any radial force on the blood vessels into which they are placed." (See col. 7, lines 37-41).

Gambale

Gambale discloses implants and delivery systems for promoting angiogenesis in ischemic tissue. The implants can be implanted into the myocardium. Gambale teaches that the implants are configured to be flexible so that they compress and expand with movement of surrounding tissue. The implants are designed so that blood flows into and out of the implant as it is compressed and expanded. The flow of blood into the implant and pooling in the implant cause formation of thrombosis. This leads to angiogenesis in the surrounding tissue. While Gambale teaches that a thrombus of blood may be loaded into the flexible implant (See col. 10, lines 55-59), Gambale does not teach or suggest that a thrombus may be disposed around the exterior of the device. Rather, the only coating discussed is an angiogenic substance (See col. 10, lines 63-64).

Gambale is not prior art to the present application under 35 U.S.C. § 103. At the time of filing of both the present application and the Gambale patent, the inventors of each were subject to an obligation to assign to C.R. Bard, Inc. According to 35 U.S.C. § 103(c)(1), subject matter developed by another person, which qualifies as prior art under 35 U.S.C. § 102(e), shall not preclude patentability where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to the obligation of assignment to the same person.

Claim Rejections Under 35 U.S.C. § 102

Reconsideration is requested with respect to the rejection of the claims under 35 U.S.C. § 102(e) as being anticipated by Berenstein. Berenstein fails to disclose every limitation of the claimed invention, as required for a rejection under 35 U.S.C. § 102(e). As noted above, Berenstein explicitly teaches that its device is made of a "material forming a long, thin threadlike device having little rigidity or column strength" (See col. 3, lines 16-18). Furthermore, "when introduced into a high-flow region, the mass quickly compacts into a significantly denser mass." (See col. 3, lines 37-38). Berenstein explicitly teaches that each of the embodiments "is an

extremely soft and flexible device, whether the device be coil or braid or chain. These devices exert little if any radial force on the blood vessels into which they are placed. They are sufficiently flexible and small that they may be carried by blood flow after ejection from the distal tip of the catheter by which they are introduced into a narrowing region in the vascular lumen where the device wedges or rolls upon itself and wedges within the blood vessel. The fluid-like properties of the device enables [sic] it to conform to the complex geometry of certain fragile, abnormal blood vessels, and in so doing, minimize the risk of causing trauma to or even perforation of those blood vessels." (See col. 7, lines 36-50). Berenstein, therefore, fails to disclose a scaffold structure which is "sufficiently rigid to support surrounding tissue and to prevent the surrounding tissue from collapsing the scaffold structure when the scaffold structure is implanted within tissue" as recited in both claims 38 and 42. Moreover, this limitation would not even be obvious over Berenstein, since Berenstein explicitly teaches that its structure must have little rigidity or column strength. Furthermore, Berenstein does not disclose an implant for treating viable tissue or a scaffold structure that is implantable and retained within the tissue. Finally, Berenstein does not disclose a scaffold that is configured to mechanically trigger an injury response leading to angiogenesis in the tissue. The fact that the Berenstein structure is so flexible that it minimizes any risk of causing trauma would prevent it from triggering an injury response. Therefore, both claims 38 and 42 are neither anticipated by nor obvious over Berenstein.

Claims 55, 57, 59, 61 and 62 were also rejected under 35 U.S.C. § 102(e) as being anticipated by Berenstein. Each of these claims is patentable over Berenstein for the same reasons as set forth above for claims 38 and 42. Moreover, claim 59 recites that the scaffold has an interior chamber in which the thrombus is loaded with the therapeutic material, and that the scaffold has openings enabling communication between the thrombus, therapeutic material and surrounding tissue. There is no teaching in Berenstein that the thrombus is located with the therapeutic material within an interior chamber and that the openings allow communication between the thrombus, therapeutic material and surrounding tissue. Rather, as noted above, Berenstein teaches that the device quickly compacts into a significantly denser mass (See col. 3, lines 37-38) which would

appear to close any openings that may exist, and prevent communication between any thrombus and therapeutic material within the Berenstein device and surrounding tissue.

Claims 63 and 65, which were newly added by this amendment, recite that the scaffold structure comprises openings that permit herniation of tissue to anchor the scaffold structure within the tissue. There is no explicit teaching of this limitation in Berenstein. Furthermore, since Berenstein teaches that when introduced into a vessel, the mass compacts into a significantly denser mass, it would appear that any openings that may have previously existed and that would arguably have permitted herniation of tissue would have been closed. Therefore, it is submitted that claims 63 and 65 are neither anticipated nor rendered obvious by Berenstein.

New claim 64 recites that the thrombus is disposed around the exterior of the device and is dependent from claim 38. It is submitted that this claim is patentable for at least the same reasons as claim 38.

Gambale was cited in rejecting claims 38 and dependant claims 53-57. Like Berenstein, Gambale fails to disclose the added limitation in claim 38 that the scaffold structure is "sufficiently rigid to support surrounding tissue and to prevent surrounding tissue from collapsing the scaffold structure when the scaffold structure is implanted within tissue." In fact, Gambale teaches just the opposite. Gambale states that "The material and structure of the implants permits [sic] them to be flexible such that the implant compresses when the surrounding tissue contracts and the implant returns to an uncompressed configuration when the surrounding tissue relaxes." (See col. 3, lines 4-8. See also col. 6, lines 2-5: "The wall 18 of the capsule may be somewhat flexible to permit flexure with the movement and compressive forces of the surrounding tissue 4 into which it is implanted.") The examiner's attention is also directed to Figures 2(B) and 2(C). Therefore, for at least this reason, claims 38 and 53-57 are not anticipated by Gambale.

New claims 63 and 64 are also not anticipated by Gambale for at least the same reasons as claim 38, from which they depend. Also, claim 64 recites that the thrombus is disposed around

the exterior of the device. Gambale does not teach that thrombus may be disposed around the exterior of the device. The only coating disclosed by Gamble is an angiogenic substance, which is not specifically disclosed to be on the exterior surface (See col. 10, lines 63-64).

35 U.S.C. § 103(a) Rejections

Claims 53, 54 and 58 have been rejected under 35 U.S.C. § 103(a) as being obvious over Berenstein in view of Ken. It is submitted that these claims, which are dependent from claims 38 and 42, are patentable for the same reasons set forth above with respect to claims 38 and 42.

Claims 56 and 60 were rejected under 35 U.S.C. § 103(a) as being obvious over Berenstein further in view of McGurk. It is submitted that these claims, which are dependent from claims 38 and 42 respectively, are patentable for the same reasons as claims 38 and 42.

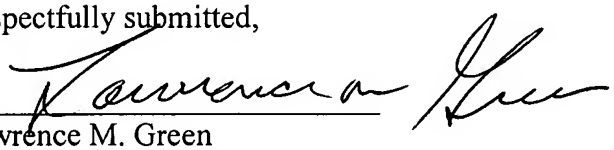
Conclusion

For the foregoing reasons, it is respectfully submitted that this amendment has placed all the claims in condition for allowance. Reconsideration and allowance of the claims are respectfully requested.

The examiner is invited to telephone applicants' undersigned attorney should he feel that such a telephone call would further the prosecution of the present application.

Dated: May 9, 2008

Respectfully submitted,

By 

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